



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

March 29, 2021

THE ADMINISTRATOR

**MEMORANDUM**

**SUBJECT:** Office of Inspector General request that the U.S. Environmental Protection Agency reconsider the Audit Dispute Resolution decision on the OIG's report No. 20-N-0128, *Management Alert: Prompt Action Needed to Inform Residents Living Near Ethylene Oxide-Emitting Facilities About Health Concerns and Actions to Address Those Concerns*, issued March 31, 2020

**FROM:** Michael S. Regan

A handwritten signature in cursive script that reads "Michael S. Regan".

**TO:** Sean W. O'Donnell  
Inspector General

In a February 22, 2021, memo to Acting U.S. Environmental Protection Agency Administrator Jane Nishida, you asked that the EPA reconsider former EPA Administrator Andrew Wheeler's dispute resolution decision related to the above-noted management alert. I have had an opportunity to review that request.

The Biden-Harris administration is committed to working to protect communities from pollution, and it is important to engage with those communities as we do our work. The EPA maintains that a decision reached in accordance with the audit dispute resolution procedures outlined in EPA Manual 2750 is final<sup>1</sup>, and the resolution of such issues is solely within the Administrator's discretion. Accordingly, former Administrator Wheeler's decision on January 4, 2021, was a final resolution of the audit dispute resolution process. Nonetheless, we have taken another look at the substantive issues underlying the dispute and have decided, on our own initiative, that this issue merits review.

We believe that it is important to share information with communities identified by the most recent National Air Toxics Assessment, released in August 2018, as having potentially elevated risks from exposure to the chemical ethylene oxide. My staff has reviewed the status of the outreach conducted since the most recent NATA was released, and I am directing several actions intended to provide residents of communities where outreach did not occur with information about potential risks from ethylene oxide exposure and the EPA's work to address those risks. I share those below for your information:

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<sup>1</sup> U.S. EPA, *Audit and Evaluation Management Manual (Manual 2750)*, March 28, 2017 version, page 33, see footnote labeled \*\*.

information about potential risks from ethylene oxide exposure and the EPA's work to address those risks. I share those below for your information:

- The emissions data on which the screening-level NATA is based is nearly seven years old, and emissions and associated risks may have changed during that time. To ensure we are providing the public with the most current information we can, I have directed EPA Regions 3<sup>2</sup>, 5 and 6 to coordinate with the states of West Virginia, Wisconsin, Louisiana and Texas as they update, or complete work to update, emissions and risk information for the specific chemical plants identified by the OIG where outreach has not been conducted. I have asked for this coordination and analysis work to be completed by the end of June 2021.
- While this work is ongoing, for the chemical plants identified by the OIG, I have asked staff in these regions to contact community leaders, including both public officials and leaders of community organizations, where available, to inform them of this work and to learn what methods of outreach the communities consider the most effective where they live – recognizing current restrictions that are necessary to slow the spread of COVID-19. The regions will invite these leaders, along with state environmental agencies, to join in planning this outreach so that it meets community needs, recognizing that the appropriate approach for one state or community may differ from that in another. In some cases, states may lead this outreach work with EPA assistance. This planning will proceed while the emissions and risk information is updated, so outreach can begin shortly afterward. In addition, as we recently shared with the OIG, the EPA Office of Air Quality Planning and Standards is scheduled to review three regulations for chemical plants by Fiscal Year 2024 and will conduct public outreach related to the results of that review as appropriate.
- The EPA will address outreach about potential risks from ethylene oxide commercial sterilizers separately from outreach about risks from chemical plants. OAQPS is updating emissions and risk information for nearly 100 commercial sterilizers in the U.S. as it develops a proposed rule for the review of the National Emissions Standard for Hazardous Air Pollutants for Ethylene Oxide Sterilization Facilities. This information will be both more recent and more refined than was available for the 2014 NATA, and we plan to share the risk results with communities where emissions from these sterilizers may pose health risk above levels that the EPA generally considers acceptable in its regulatory work. We expect that outreach will occur later this summer, provided the analysis work has been completed.
- We recognize that neither the EPA nor state outreach occurred in three communities that were identified in NATA as having potentially elevated risks and where commercial sterilizers were the major ethylene oxide emitters. I have asked staff in EPA Regions 3 and 6 to reach out to leaders in the Pennsylvania Department of Environmental Protection and the Texas Commission on Environmental Quality to let them know about this work and to

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<sup>2</sup> For the Croda facility in New Castle, Delaware, the Delaware Department of Natural Resources and Environmental Control is leading risk communication work and has held public meetings. We expect that DNREC will continue to be the lead on issues related to this facility; however, EPA Region 3 is committed to hold discussions on how to best support the community and advise on environmental justice issues.

identify local and community leaders to participate in the outreach planning. Separately, I also am asking Region 6 staff to ensure that leaders in the New Mexico Environment Department are made aware of the upcoming analysis work, so they will be prepared to assist with outreach in the event the analyses for the sterilizer NESHAP indicate that risks may be elevated in that community.<sup>3</sup>

- In Region 2, where a scheduled public meeting in a community near a commercial sterilizer had to be postponed last spring because of the COVID-19 emergency, I have asked staff to let both the Puerto Rico Department of Environment and Natural Resources and local officials know that the EPA is updating emissions and risk information for sterilizers and will be coordinating with them, along with community leaders, to restart outreach planning in the coming months.

We would be happy to meet with you to discuss this issue further.

cc: Joseph Goffman  
Peter Tsirigotis  
Mike Koerber

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<sup>3</sup> The OIG identified a census tract in Santa Teresa in its March 2021 Management Alert. Although the 2014 NATA analysis indicated risks from air toxics exposure in that tract were 200 in one million based on 2014 emissions, the NATA map and documentation also included information noting that emissions from the commercial sterilizer in that census tract had been reduced by 83 percent between 2014 and 2018, when NATA was released.